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Methodology to Insure U.S. Genetically Modified (GM) Grain Sales into Approved Foreign Markets - Integrating ISO Traceability Standards with Agricultural Quality Management Systems (QMS)

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Situation

Expansion and rapid introduction of new transgenic events will be critical elements in increased grain production, which is needed to fill rising world food and energy demands. The US approval process for biotech products is likely to continue to operate faster than that of our major customer nations, potentially creating market disruptions, and artificial barriers to trade. Most likely, new GM events will be used to create increased yield, although GM quality trait events are also being developed. A workable quality management system framework, supported by specific procedures and practices as needed to satisfy individual markets, could provide the customer assurance necessary for US production to move forward with fewer problems.

Introduction background

The Iowa Grain Quality Initiative group, have been developing the theory and practice of traceability of grains, from farmer and receiving elevators to the end users, for several years. Iowa State University has also played a major role in the ongoing development of the ISO 22006 standard, quality management systems for production agriculture. This project incorporates previous ISU work into a quality management based structure with accompanied suggested supporting documentation for corn and soybean production and its bi-products (e.g., DDGS). We are creating a methodology that does not mandate changes, but one that accounts for traceability and flow of essential data in specific cases. The traceability of all grains, especially GMOs (to include partially and incompletely approved GMO varieties), will become increasingly important to retain the value of traits or segregate them from commercial grain marketing channels due to customer requirements.

Iowa State scientists have been developing the theory and practice of traceability for agricultural products. This project will incorporate these results into a management structure (NOVECTA's QPMS and ISO 22005/22006), and potential operating practices for corn and soybean production and marketing. Because customer perception (rather than scientific reality) is a major element of the GM concerns worldwide, the existence of an organized and practical process by which US-only approved events can be grown/handled should generate favorable public relations. In addition, costs of testing and other more costly interventions could be minimized.

The best Quality Management System (QMS) applications are those that start in response to a business problem, and gradually demonstrate their value over time in cost/benefits and efficiency. For example, incompletely approved GM is best first addressed with a set of guidelines and best practices, with more specific steps/documentation in cases of more stringent demands (e.g.

0.5% GM versus 5.0% GM allowances). The tracking/monitoring of raw materials through to customer processing/products is a basic strength of the QMS process, without requiring any more effort and recordkeeping than the specific situation warrants. This project will not design or require an unknown QMS system to be incorporated for farmer use. It will take NOVECTA's already developed and accepted QPMS and create an export focused protocol that integrates ISO 22005/22006 standards: For the goal of facilitating corn and soybean exports.

Ultimately, a supply chain's success is defined by delivering products (appropriately traceable) to users in the condition and manner promised, which is a total system consideration. Any overlooked operation adds to the uncertainty that products will be as desired, with the purity as required, and with minimum impact on surrounding producers. This project will provide a comprehensive traceability standardization infrastructure (transparency of critical data, as needed throughout the supply chain). This will also include compliance and cost/benefit measurement tools that will be formally incorporated within NOVECTA's offered services.

Objectives

This project will create a cost effective framework protocol for documenting production of either incompletely approved GMO corn or contracted non-GMO corn and soybeans so that essential data will be available to satisfy specific customer needs. The overall goal is to provide US corn and soybean producers increased access to foreign markets, especially for incomplete or partially approved GMOs and GMO co- and bi-products (e.g. DDGS).

Materials

The materials to be used will include NOVECTA's QPMS program and the introduction of the new, internationally accepted, and recognized ISO 22000 Food Safety Management System with the new 22006 Production Agriculture series. ISO 22006 blends the strengths of interactive supply chain communications (data flow transparency), with NOVECTA's QPMS prerequisite program, and another internationally recognized system—Hazard Analysis and Critical Control Point (HACCP) system. By means of auditable requirements, ISO 22006 combines ISO standardization and NOVECTA's QPMS prerequisite program, which will promote and accelerate the exportation of US GMO grains and their co and bi-products. In addition, participating farmers will utilize ISU created compliance and cost/benefit templates and spreadsheets used to analyze and interpret data.

Methods and procedures

Performance measures are at the operational and evaluation levels. Operational outputs are specific items (with supporting explanation, support and user interface) to be used in setting up the system. Protocol measurement tools will delve into greater details of the new protocol (of the blended QPMS and ISO standards). Many of the following are nearly or already completed and include:

- Process map of corn production operations (to include DDGS), seed to user, showing points at which control or documentation is needed (in varying intensity as the situation dictates) to maintain purity assurances. This can be applied either to the incompletely approved GM to bulk markets, or to the non-GM for specific markets. We have already contributed to the creation of an internationally accepted process (operations) mapping procedure), and are currently applying it to a feed-to-milk production chain.
- Checklist methodology for self-assessment and/or third-party assessment.
- Example procedures for critical operations following process map.
- Recordkeeping—quality manual style template that can be user configured to the level of detail needed for a given case. This project will not develop or promote the application of a complete ISO-formatted quality management system, but all the items created will be of the style and format that could be incorporated in an ISO system if desired.

Evaluation measurement outputs are in the form of two interrelated spreadsheets and analyses, i.e. traceability compliance scorecard and the cost-benefit spreadsheet. The traceability compliance scorecard represents effectiveness of the protocol, while the cost-benefit spreadsheet evaluates its costs efficiency. Data for both spreadsheets are derived from protocol specifications and participating farmers.

Project results

Development of a protocol (ISO) to help facilitate exportation of US corn and soybeans (and corn co and bi-products), and the ability of the protocol to be audited and trained. This protocol framework comprises:

- Develop process maps for corn and soybean production/marketing.
- Design a self-study checklist for users to evaluate their present practices. Traceability compliance scorecard set-up and analysis; case study examples presented. The three category areas of interest are:
- Create example sets of work instructions/procedures for case study situations; in this case production of new GM corn varieties, assuming 2-4 scenarios with appropriate export status (approved).
- Develop a basic producer-oriented traceability instruction and training program, either self-study or to be offered through private contractors.
- Present the cost-benefit spreadsheet format and analysis with case study examples. This will offer comparisons of production costs tied to purity levels required.

The traceability scorecard—provides an effectiveness evaluation of traceability compliance; i.e., comparing the standard (specified—required documentation, procedures, and data) to what is actually accomplished. An example is given below. This can be as complex or simple as the situation and the process map warrant.

Table 1. Example of a traceability scorecard

Scorecard Matrix			Std (required)			Measured (actual)			Difference		
			Breadth	Depth	Accuracy	Breadth	Depth	Accuracy	Breadth	Depth	Accuracy
IPT Trait(s) / Attribute(s) Success Scorecard (e.g., organic product, fair-wage, pasture-fed, etc.)	= □	1) Controlling Std (contract/Regs.)									
		A) Seed Purity (98%)									
		(i) Output Purity ± 0.002-0.005	1	3	0.980	1	3	0.978	1.00	1.00	0.9980
		(ii) Other purity data (pts.)	1	1		1	1		1.00	1.00	
		B) Tolerance Level (pts.)	1	1		1	1		1.00	1.00	
		(i) Other tolerance data									
	* □	2) Performance Measurement Entity/Parameters									
B = Breadth		A) Primary Entity (farmer, etc.)									
(actual number of measurements and/or data points)		(i) Inputs (pts.)	2	3		1.0	3.0		0.50	1.00	
		(a) Seed purity-98.0%									
		(ii) Operations (pts.)	200	4		185.0	3.1		0.93	0.78	
		(a) Chemicals data									
		(b) Storage									
		(c) Cleanouts									
D = Depth		(d) Inspections crop/field			0.98			0.9800			1.0000
1 = farmer		(iii) Tests (pts.)	15	3		13.5	2.2		0.90	0.73	
2 = farmer + 1 entity		(a) Field tests (A)			0.98			0.9600			0.9796
		(b) Laboratory tests (A)			0.98			0.9750			0.9949
3 = farmer + 2 entities		(iv) Administrative (pts.)	50	3		45.0	2.0		0.90	0.67	
		(a) Training periods									
		(b) Data collection									
A = Accuracy		(c) Inspection, records									
(degree of conformity and/or measurement parameters; determined by tests, audits, etc.)		(v) Certification (pts.)	1	3		1.0	3.0		1.00	1.00	
		(a) Organic									
		(b) ISO									
		B) Buyer inspections									
		(i) Operational (pts.)	8	4		4.8	3.2		0.60	0.80	
		(ii) Administrative (pts.)	7	3		5.2	2.1		0.74	0.70	
		(iii) Tests (A)			0.98			0.9700			0.9898
		C) Third-Party inspections									
		(i) Operational (pts.)	20	4		14.9	3.7		0.75	0.93	
		(ii) Administrative (pts.)	15	3		13.0	2.0		0.87	0.67	
		(iii) Tests (A)			0.98			0.9780			0.9980
		D) Grader (pts.)	5	2		4.5	2.0		0.90	1.00	
	* □	3) Communications (Producer/Buyer)									
		A) Production Nomenclature (pts.)	25	3		22.0	2.4		0.88	0.80	
		(i) Unit size									
		(ii) Product									
		(iii) Other inputs/Byproducts									
		B) Attribute(s)/Trait(s) (pts.)	50	3		46.5	2.1		0.93	0.70	
		(i) Data/process(s) of interest									
		(ii) Measurements									
		(iii) Test Methodology									
									Weighted Average Score		
		Accuracy Range (Min, Max)				0.960	0.980		0.901	0.895	

The cost-benefit spreadsheet—provides an extensive, but not exhaustive, statistical summation that focuses on soybean specific traceability production cost components and revenue data, as applied to varying purity levels of crop production (for comparative purposes).

Table 2. Example of the cost-benefit spreadsheet

Back Ground Information		Input cells are shaded				
Item	**Measure Units**	**Std.**	**Trace 1**	**Trace 2**	**Trace 3**	**Trace 4**
Personal Information						
ID Number		1	2	3	4	5
Name		Bill Smith				
Address						
Phone #						
Email						
Other						
General Information						
Crop Planted		Corn	Corn	Corn	Corn	Corn
Crop Variety Planted			XYZ	XYZ	XYZ	XYZ
Purity Level (Required)	**%**	**n/a**	**5.0%**	**2.0%**	**1.0%**	**0.1%**
Crop Acres	acres	200	200	200	200	200
GIS Acreage Data	n/a					
Grain Yield	bu/acre	195	195	195	195	195
Previously Planted Crop in Field		Soybeans	Soybeans	Soybeans	Soybeans	Soybeans
Type of Trace System		None	New	New	New	New
Trait(s) and/or Attribute(s) of Interest		None	GMO	GMO	GMO	GMO
Other						
Hourly Wage Information						
Management	$/hr	$25.00	$25.00	$25.00	$25.00	$25.00
Labor	$/hr	$15.00	$15.00	$15.00	$15.00	$15.00
Meeting, Off Season	$/hr	$40.00	$40.00	$40.00	$40.00	$40.00
Contract or Hired Professional	$/hr	$50.00	$50.00	$50.00	$50.00	$50.00
Other		$0.00	$0.00	$0.00	$0.00	$0.00
Operating Assumptions						
Grain Hauling, Semi	$/mile	$0.250	$0.250	$0.250	$0.250	$0.250
Interest, Carry-on Operating Money	%/yr	8.00	8.00	8.00	8.00	8.00
Capital Interest	%/yr	6.00	6.00	6.00	6.00	6.00
Personal travel mileage	$/mile	$0.500	$0.500	$0.500	$0.500	$0.500
Personal travel meal expense	$/day	$50.00	$50.00	$50.00	$50.00	$50.00
Personal travel overnight expense	$/day	$100.00	$100.00	$100.00	$100.00	$100.00
Other		$0.00	$0.00	$0.00	$0.00	$0.00